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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/377,795	08/20/1999	MICHAEL KARIN	P-UD-3613	8313

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/377,795	KARIN ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13-15 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *13-15* is/are allowed.

6)☒ Claim(s) *11 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 3, 2005 has been entered.

Information Disclosure Statement

The Examiner thanks Applicant for the submission of new copies of the references previously cited on an IDS. The references have been considered.

Oath/Declaration

The newly executed Oath of Inventor Zandi filed May 3, 2005 is accepted.

Claim Rejections - 35 USC § 112

The new matter rejection set forth in the previous action for the recitation of "at least 87%" identity to SEQ ID NO: 2" is withdrawn. The recitation of at least 90% identity is supported by the specification.

Claim 11 is maintained as rejected and new claims 31-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 11 has been amended to recite that the claimed IKK-γ nucleic acid encodes a polypeptide that has at least 90% amino acid identity with SEQ ID NO: 2 and has one or more biological activities of a full-length IKK-γ polypeptide. Claims 31-34 depend from claim 11 and contain all limitations of this claim.

Nucleic acids that encode peptides having at least 90% amino acid identity to SEQ ID NO: 2 constitute a large genus of compounds and include sequences where the region of non-identity occurs in one area of the sequence and where the area of non-identity is interspersed throughout the sequence in either a regular or random fashion. The polypeptide resulting from this situation might have amino acid sequences quite different from that of SEQ ID NO: 2.

The instant specification describes the isolation of IKK-γ and describes several biological activities of IKK-γ. The specification further describes how these biological activities are affected by fragments of IKK-γ having either C- or N-terminal deletions. The specification does not describe nor is it known in the prior art what amino acids constitute the critical residues of IKK-γ that produce these biological functions such that the skilled artisan could envision which amino acids can be altered and still produce a

structure that retains the recited biological functions of IKK-γ. For example, if the structure of one or more domains or motifs present in SEQ ID NO: 2 is known to be responsible for the function of IKK-β binding activity, the skilled artisan would be able to readily ascertain the structures of nucleic acids that encode a polypeptide 90% identical to SEQ ID NO: 2 and retain the function of binding IKK-β. Absent such knowledge, the genus of compounds that have both 90% identity to SEQ ID NO: 2 and a biological function of IKK-γ is not adequately described.

In order for the written description provision of 35 USC 112, first paragraph to be satisfied, applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. For example, MPEP 2163 states in part,

> "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")."

The skilled artisan cannot envision the detailed structure of the encompassed nucleic acids that will encode a polypeptide that is 90% identical to SEQ ID NO: 2 that additionally retains a biological function of the full-length IKK-g, regardless of the complexity or simplicity of the method of isolation.

Therefore, the full breadth of the nucleic acids encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant.

Response to Arguments - 35 USC § 112

Applicants contend that the claim amendments submitted May 3, 2005 obviate the new matter and written description rejections. The amendments do overcome the new matter rejection and find support in the specification, but the amendments do not overcome the written description rejection for the reasons set forth in the rejection.

New Claim Rejections - 35 USC § 112

The indicated allowability of claim 30 is withdrawn in view of the new rejections that follow.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 30 is directed to a human origin antisense polynucleotide comprising a nucleotide sequence complementary to SEQ ID NO: 1. Claim 30 encompasses

polynucleotides of any length. The specification discloses on pages 4 and 31 that the antisense polynucleotides of the invention are complementary to at least nine contiguous nucleotides of SEQ ID NO: 1 and on page 33 that an antisense polynucleotide can be the full length of SEQ ID NO: 1. No support for antisense polynucleotides of less than nine contiguous nucleotides can be found in the specification.

Additionally, no support can be found in the specification for "human origin" antisense polynucleotides. The specification does not describe the characteristics of an antisense polynucleotide of human origin that would distinguish it from an antisense polynucleotide not of human origin. If Applicant believes support exists for these limitations, it should be pointed out by page and line number in the response to this Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 30 is rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al. (database results of STIC sequence search, US-09-377-795-1.rst, January 12, 2001, result 4, accession number AA402683, of record).

1. Claim 30 is directed to a human origin antisense polynucleotide comprising a sequence complementary to SEQ ID NO: 1.

2. Result # 4 of the database search of SEQ ID NO: 1 discloses a 572 bp human nucleic acid containing a region complementary to more than 500 contiguous nucleotides of SEQ ID NO: 1 was disclosed to the public by Hillier et al. on November 9, 1997.

3. Thus, Hillier et al. disclose all limitations of and anticipate claim 30.

Allowable Subject Matter

Claims 13-15 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
June 17, 2005

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